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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,781	04/20/2005	Saeed R. Khan	018890-000810US	8804

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
NWAONICHA, CHUKWUMA O	
ART UNIT	PAPER NUMBER
1621	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,781	KHAN, SAEED R.	
	Examiner	Art Unit	
	CHUKWUMA O. NWAONICHA	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-12 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13 and 14* is/are rejected.

7)☒ Claim(s) *2-9 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending in the application.

Election/Restrictions dated 09/14/2007 has been regrouped into two inventions following Applicants argument: Group 1, claims 1-9, 13 and 14 drawn to a compounds of formula I and method of treating diseases; classified in class 562, subclass 7+ Group 1, claims 10-12 and 15-21 drawn to a compounds of formula II and method of treating diseases; classified in class 562, subclass 7+.

Election/Restrictions

Applicant's election with traverse of Group 1 (claims 1-9, 13 and 14) in the reply filed on 14 January 2008 is acknowledged.

The traversal is on the ground(s) that claims 1-21 are related as a single invention. Groups 1 and 2 are drawn to different compounds. The two Groups are different from one another and therefore, they are different inventions, and require different search strategies that will impose an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made **FINAL**.
Group 2 (claims 10-12 and 15-21) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups, there being no allowable generic or linking claim. All claims consisting of Group 1 (claims 1-9, 13 and 14) drawn to a compounds of formula I and method of treating diseases, will be examined on the merits. Applicants are reminded of their right to file divisional applications to the non-elected claims.

Applicants' are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Objection

Claim 14 is objected because there is no period **(.)** at the end of the claim. Correction is required.

Claim Rejections - 35 USC § 102

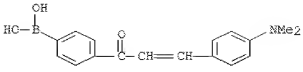
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated DiCesare et al., {Chalcone-analogue fluorescent probes for saccharides signaling using the boronic acid group, Tetrahedron Letters (2002), 43(14), 2615-2618}.

DiCesare et al. disclose applicants' claimed compound wherein the variable Ar is substituted with heteroalkyl group as shown below.



Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically "compounds of formula I and their pharmaceutically acceptable salts thereof, and for treating human breast cancer" does not reasonably provide enablement for "the resolved enantiomers, diastereomers, solvates of compounds of formula I and for treating any tumor or any cancer, and for treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia" as claimed.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. § 2164.

In the instant case, the claims cover "the resolved enantiomers, diastereomers, solvates of compounds of formula I and for treating any tumor or any cancer, and for treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia". Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to practice this invention without undue experimentation. See M.P.E.P. 2164.01. Given the lack of disclosure for "the resolved enantiomers, diastereomers, solvates of compounds of formula I and for treating any tumor or any cancer, and for treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer,

mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia", the instant invention cannot be practiced commensurate in scope with the claims.

The Examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a)). However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention from the claim to "the resolved enantiomers, diastereomers, solvates of compounds of formula I and for treating any tumor or any cancer, and for treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia".

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Based on the forgoing, **claims 1, 13 and 14** are *prima facie* non-enabled for their full scope.

With regard to rejection under 35 U. S. C. 112, first paragraph, the following factors have been carefully considered (***In re* Wands**, 8 USPQ2d 1400; CAFC, 1988):

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

(1) **Nature of the invention.** As indicated above, the invention is drawn to "the resolved enantiomers, diastereomers, solvates of compounds of formula I and for treating any tumor or any cancer, and for treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia".

(2) **Breadth of the Claims.** The claims are extremely broad. In particular, **claims 1, 13 and 14** that read on specifically "the resolved enantiomers, diastereomers, solvates of compounds of formula I and for treating any tumor or any cancer, and for treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia".

(4) **Unpredictability of the Art.** The instant case is drawn to "the resolved enantiomers, diastereomers, solvates of compounds of formula I and for treating any

tumor or any cancer, and for treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia". Applicants' claim to "the resolved enantiomers, diastereomers, solvates of compounds of formula I and treating any tumor or any cancer, and treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia" is doubtful and requires objective proof. In such a speculative field, more enablement by way of specific examples is necessary in order to establish the utility of a genus. In re Fisher, 166 U.S.P.Q. 18.

(5) **Amount of Guidance Provided.** Applicants have not provided guidance as how to employ the resolved enantiomers, diastereomers, solvates of compounds of formula I and how to treat any tumor or any cancer, and how to treat the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell

carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia. However, when considering that the claims read on "the resolved enantiomers, diastereomers, solvates of compounds of formula I and for treating any tumor or any cancer, and for treating cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia", it becomes critical to know the resolved enantiomers, diastereomers, solvates of compounds of formula I and how to treat any tumor or any cancer, and the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia that applicants are claiming. This is critical to the practice of the invention and therefore should adequately be disclosed.

(7) **Ordinary Skill in the Art.** The ordinary skill artisan would not be able to utilize the resolved enantiomers, diastereomers, solvates of compounds of formula I for treating any tumor or any cancer, and for treating the following cancer: cervical,

stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia that applicant are claiming.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for "the resolved enantiomers, diastereomers, solvates of compounds of formula I for treating any tumor or any cancer, and for treating the following cancer: cervical, stomach, colon, bladder, rectal, liver, pancreatic, lung, cervix uteri, corpus uteri, ovary, prostate, testis, renal, brain/cns, head, neck, throat, anal and oral cancers, eye or ocular cancer, skin melanoma, Ewing's Sarcoma, Kaposi's Sarcoma, basal cell carcinoma and squamous cell carcinoma, small cell lung cancer, mouth/pharynx, esophageal, larynx, kidney and lymphoma, acute lymphocytic leukemia, and acute myelogenous leukemia that applicant are claiming".

Allowable Subject Matter

Claims 2-9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is

571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chukwuma O. Nwaonicha/
Examiner, Art Unit 1621

/Sikarl A. Witherspoon/
Primary Examiner, Art Unit 1621

(for)

Yvonne (Bonnie) Eyler
Supervisory Patent Examiner,
Technology Center 1600